DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 99M–1521, 99M–1980, 99M–1696, 99M–1981, 99M–2028, 99M–1520, 99M–1982, 99M–0150, 99M–0255, 99M–2016, 99M–2015, 99M–0871, 99M–0870, 99M–1851]

Medical Devices; Availability of Safety and Effectiveness Summaries for PMA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket application (PMA) approvals. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMA's through the Internet and the agency's Dockets Management Branch.

ADDRESSES: Summaries of safety and effectiveness are available on the Internet at http://www.fda.gov/cdrh/pmapage.html. Copies of summaries of safety and effectiveness are also available by submitting a written request to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 in the **SUPPLEMENTARY INFORMATION** section of this document when submitting a written request.

FOR FURTHER INFORMATION CONTACT: Kathy M. Poneleit, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2 186.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule to revise §§ 814.44(d) and 814.45(d) (21 CFR 814.44(d) and 814.45(d)) to discontinue publication of individual PMA approvals and denials in the **Federal Register.** Revised §§ 814.44(d) and 814.45(d) state that FDA will notify the public of PMA approvals and denials

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by posting them on FDA's home page on the Internet at http://www.fda.gov; by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch; and by publishing in the **Federal Register** after each quarter a list of available safety and effectiveness summaries of approved PMA's and denials announced in that quarter.

FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register.**

In accordance with Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The following is a list of approved PMA's for which summaries of safety and effectiveness were placed on the Internet in accordance with the procedure explained previously from April 1, 1999, through June 30, 1999. There were no denial actions during this period. The list provides the manufacturer's name, the generic name or the trade name, and the approval date.

TABLE 1 .-LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE APRIL 1, 1999, THROUGH JUNE 30, 1999

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P870072(S5)/99M–1521	Thoratec Laboratories Corp.	Thoratec® Ventricular Assist Device	May 21, 1998
P970061/99M–1980	Boston Scientific–SCIMED	SCIMED Radius Coronary Stent with Delivery System	July 16, 1998
P980001/99M–1696	Boston Scientific Corp.	NIR ON™ Ranger™ Premounted Stent System	August 11, 1998

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMA'S MADE AVAILABLE APRIL 1, 1999, THROUGH JUNE 30, 1999—Continued

PMA Number/Docket No.	Applicant	Trade Name	Approval Date
P970024/99M–1981	Angeion Corp	Defibrillator (ICD) System and the Angeflex™ Defibrillation Lead System	August 19, 1998
P980009/99M–2028	Boston Scientific Corp.	Magic Wallstent Endoprothesis	September 29, 1998
P920014(S7)/99M–1520	Thermo Cardiosystems, Inc.	Heartmate® VE LVAS	September 29, 1998
P960006/99M–1982	Guidant Corp.	Sweet Tip® Rx Steroid Eluting Lead	October 2, 1998
H980005/99M–0150	NeuroControl Corp.	VOCARE® Bladder System	December 28, 1998
H980008/99M–0255	NeuroControl Corp.	VOCARE® Bladder System	February 19, 1999
P980003/99M–2016	Cardiac Pathways Corp.	Chilli® Cooled RF Ablation System	February 2, 1999
P980037/99M–2015	Possis Medical, inc.	Angiojet Rheolytic Thrombectomy LF140	March 12, 1999
P850020(S11)/99M–0871	Cypress Bioscience, Inc.	Prosorba™ Column	March 15, 1999
P920023(S7)/99M–0870	American Medical Systems, Inc.	Jrolume Endoprosthesis	March 29, 1999
P960016/99M–1851	Daig Corp.	Radio Frequency-Powered Cardiac Catheter Ablation System	May 4, 1999

Dated: 11/24/99
November 24, 1999

Linda S. Kahan
Deputy Director for Regulations Policy
Center for Devices and Radiological Health

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